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Total Number of Pages in This Submission

Application Number	10/574,167
Filing Date	March 29, 2006
First Named Inventor	BUSH et al.
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	8028-007-US

Total Number of Pages in This Submission

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Firm Name	CATALYST LAW GROUP, APC		
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Printed name	Michael B. Farber, Ph.D., Esq.		
Date	June 8, 2006	Reg. No.	32,612

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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Examiner: To Be Assigned
Bush et al.)	Group Art Unit: To Be Assigned
Serial No.: 10/547,176)	Docket No.: 8028-007-US
Filed: March 29, 2006)	Date Mailed: June 8, 2006
For: USE OF CELL LINES TO PRODUCE ACTIVE THERAPEUTIC PROTEINS)	

INFORMATION DISCLOSURE STATEMENT

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Dear Sir:

This document is an Information Disclosure Statement to the above-cited patent application.

Attached is at least one form PTO/SB/08A/B listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b), the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.96, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned at (858) 450-0099 x302 so that any deficiencies can be remedied.

This Information Disclosure Statement is being submitted within three months of the filing date of the above-identified patent application. Accordingly, no fee is due for the filing of this Information Disclosure Statement under 37 C.F.R. § 1.97(b)(1).

A copy of each document is enclosed, except for issued United States patents and published United States patent applications pursuant to 37 C.F.R. § 1.98(a)(2)(ii). Some of the documents may have markings thereon. No significance is to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import, as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the prosecution of this application; and (2) represented on any patent which may issue on the application. Applicant respectfully requests that copies of the forms PTO/SB/08A/B, as considered and initialed by the Examiner, be returned with the next communication.

U.S. Patent No. 5,665,589 to Harris et al., issued on September 9, 1997.

U.S. Patent No. 6,046,050 to Strauss et al., issued on April 4, 2000.

U.S. Patent No. 6,107,043 to Jauregui et al., issued on August 22, 2000.

U.S. Patent No. 6,517,830 to Lollar et al., issued on February 11, 2003.

U.S. Patent No. 6,806,351 to Ruben et al. issued on October 19, 2004.

U.S. Patent Application Publication No. 2002/0045262 by Prachumsri, published on April 18, 2002.

PCT Patent Application Publication No. WO 99/55853 by Fukaya et al., published on November 4, 1999, which describes a novel immortalized hepatic cell line originating in normal human (preferably human fetal) cells, a process for producing this cell line; a method for screening compounds or salts thereof capable of inhibiting or promoting the activity of an enzyme participating in the metabolism of a biological foreign matter in the liver, inhibiting or promoting the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, or inhibiting or promoting the induction of the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, the process involving using the above-mentioned cell line. The application further describes compounds capable of inhibiting or promoting the activity of an enzyme participating in the metabolism of a biological foreign matter in the liver, compounds capable of

inhibiting or promoting the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, compounds capable of inhibiting or promoting the induction of the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, or salts of these compounds obtained by the above screening method. The cell line is described as useful in, for example, screening compounds having preventive/therapeutic effects on liver failure.

A publication, J.B. Mills et al., "Induction of Drug Metabolism Enzymes and MDR1 Using a Novel Human Hepatocyte Cell Line," *J. Pharm. Exp. Therap.* 309: 303-309 (2003).

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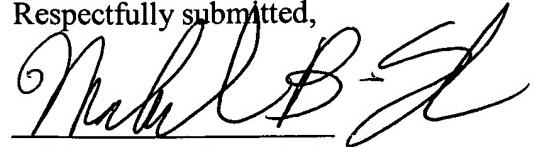
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Date: June 8, 2006

Respectfully submitted,



Michael B. Farber, Ph.D., Esq.
Reg. No.: 32,612

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		Filing Date	March 29, 2006
		First Named Inventor	BUSH et al.
		Art Unit	TBD
		Examiner Name	TBD
		Attorney Docket Number	8028-007-US
Sheet	1	of	1

U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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		A.S. NIES & S.P. SPIELBERG, "Principles of Therapeutics" in J.G. Hardman & L.E. Limbird, eds., "Goodman &...," (9th ed., McGraw-Hill, New York, 1996), ch. 3., pp. 43-62.	

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NON PATENT LITERATURE DOCUMENTS				
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		ZOLA et al., in Monoclonal Hybridoma Antibodies: Techniques and Applications (Hurell, ed., CRC Press, 1982), pp. 51-52.		
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		E. LECLUYSE et al., "Cultured Rat Hepatocytes" in Models for..., (R.T. Borchard et al., eds., P.L Smith & G. Wilson, Plenum Press, New York, 1996), ch. 9., pp. 121-160.			
		E. LECLUYSE et al., "Strategies for Restoration and Maintenance of Normal Hepatic Structure and Function in Long-Term Cultures...", Adv. Drug Delivery Rev. 22: 133-186 (1996).			
		D. MUDRA & A. PARKSINSON, "Preparation of Hepatocytes for..." in Current Protocols in Toxicology Unit 5.8. (M Maines et al., eds., John Wiley & Sons, Inc. 2001), Unit 5.8.			
		A. MADAN et al., "Effect of Cryopreservation on Cytochrome P450 Enzyme Induction in Cultured Rat Hepatocytes," Drug Metab. Dispos. 27: 327-335 (1999).			
		E. LECLUYSE et al., "Influence of Extracellular Matrix Overlay and Medium Formulation on the Induction of Cytochrome P450 2B in...," Drug Metab. Dispos. 27: 909-915 (1999).			
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		A. ABID et al., "Expression and Inducibility of UDPglucuronyltransferases by 1-Naphthol in Human Cultured Hepatocytes and Hepatocarcinoma...," Life Sci. 60: 1943-1951 (1997).			
		A.M. BACIEWICZ et al., "Update on Rifampin Drug Interactions," Arch. Intern. Med. 147: 565-568 (1987).			
		G. BERTILSSON et al., (1998) "Identification of a Human Nuclear Receptor Defines a New Signaling Pathway for CYP3A...," Proc. Natl. Acad. Sci. USA 95: 12208-12213 (1998).			

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Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/574,167
				Filing Date	March 29, 2006
				First Named Inventor	BUSH et al.
				Art Unit	TBD
				Examiner Name	TBD
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		M.D. BURKE et al., "Ethoxy-, Pentoxy- and Benzyloxyphenoazones and Homologues: A Series of Substrates to Distinguish Between...," Biochem. Pharmacol. 34: 3337-3345 (1985).			
		P.S. EIS et al., "An Invasive Cleavage Assay for Direct Quantitation of Specific RNAs," Nature Biotechnol. 19: 673-676 (2001).			
		S.S. FERGUSON et al., "Regulation of Human CYP2C9 by the Constitutive Androstane Receptor: Discovery of a New Distal Binding Site," Mol. Pharmacol. 62: 737-746 (2002).			
		A. GEICK et al., "Nuclear Receptor Response Elements Mediate Induction of Intestinal MDR1 by Rifampin," J. Biol. Chem. 276: 14581-14587 (2001).			
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		A.P. LI et al., "Primary Human Hepatocytes as a Tool for the Evaluation of Structure-Activity Relationship in Cytochrome P450...," Chem. Biol. Interact. 107: 17-30 (1997).			
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		J.M PASCUSSI et al., "The Expression of CYP2B6, CYP2C9 and CYP3A4 Genes: A Tangle of Networks of Nuclear and Steroid Receptors," Biochim. Biophys. Acta 1619: 243-253 (2003).			
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		J. SAHI et al., "Avasimibe Induces CYP3A4 and Multiple Drug Resistance Protein 1 Gene Expression Through Activation...", J. Pharmacol. Exp. Ther. 306: 1027-1034 (2003).			
		E.G. SCHUETZ et al., "Modulators and Substrates of P-Glycoprotein and Cytochrome P4503A Coordinately Up-Regulate These Proteins...", Mol. Pharmacol. (49): 311-318 (1996).			
		A.J. SONDERFAN et al., "Regulation of Testosterone Hydroxylation by Rat Liver Microsomal Cytochrome P-450," Arch. Biochem. Biophys. 255: 27-41 (1987).			
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		E. SPINA et al., "Clinically Significant Pharmacokinetic Drug Interactions with Carbamazepine: An Update," Clin. Pharmacokinet. 31: 198-214 (1996).			
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		A.J. WILLIAMS et al., "Comparative Metabolic Capabilities of CYP3A4, CYP3A5, and CYP3A7," Drug Metab. Dispos. 30: 883-891(2002).			
		A.W. Wood et al., "Regio- and Stereoselective Metabolism of two C19 Steroids by Five Highly Purified and Reconstituted Rat...", J. Biol. Chem. 258: 8839-8847 (1983).			

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